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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/578,603

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Jonathan Duffield

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/578,603	<b>Applicant(s)</b> DUFFIELD ET AL.	
	<b>Examiner</b> Jeffrey E. Russel	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 5-20 and 23-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 20 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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1. Applicant's election of the invention of Group I, claims 1-4, 21, and 22, in the reply filed on September 8, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 5-20 and 23-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 8, 2009.

2. The abstract of the disclosure filed March 17, 2010 is objected to because at line 8, "dimer" is misspelled. Correction is required. See MPEP § 608.01(b).

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure supporting the new claim limitation in claim 4 that the sugar can be an aldose, a cyclic sugar, a dialdose, a ketodalose, a saccatriose, or a gloside. Disclosure of a genus as broad as "carbohydrate" does not indicate that Applicants contemplated and had within their possession each of the specific carbohydrates recited in claim 4, and does not provide explicit, implicit, or inherent support for the new claim limitation. Applicants have not indicated where the original disclosure of the invention supports the new claim limitation.

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4. Claims 1-4, 21, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Formula I recited in claim 1 is unclear. When  $n$  is an integer greater than 1, the formula does not provide  $\text{NH}$  and  $\text{C}(=\text{O})$  groups for each  $\text{R}_5$ . It is unclear if  $\text{NH-R}_4\text{-C}(=\text{O})$  and  $\text{NH-R}_5\text{-C}(=\text{O})$  of Formula I constitute amino acid residues, or if  $\text{R}_4$  and  $\text{R}_5$  by themselves are amino acid residues to which the formula requires the attachment of an additional  $\text{NH}$  group at their N-termini and of an additional  $\text{C}(=\text{O})$  group at their C-termini. The Markush group recited in claim 4 is unclear because “carbohydrates” and “saccharides” do not appear to be species of the amino sugar, deoxy sugar, or sialic acid sugar being defined in the claim. The terms “carbohydrates” and “saccharides” are not specific types of the amino sugars, deoxy sugars, or sialic acid sugars being defined in the claim, but rather are a genus of compounds of which amino sugars, deoxy sugars, and sialic acid sugars are members. Claim 4 recites “ketodaloses”, “saccatrioses”, and “glosides”. However, these appear to be misspellings, because no definition for these words can be found, either in the specification or the prior art. It is not clear what compounds Applicants intend to recite in the claim.

5. Claims 1-4, 21, and 22 are objected to because of the following informalities: At claim 1, line 9, the comma after “by” should be deleted. At claim 4, line 3, “or” should be inserted before “acidic”. At claim 4, line 5, “or” should be changed to “and” so that standard Markush terminology is used. Appropriate correction is required.

6. Applicant is advised that should claim 1 be found allowable, claim 4 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight

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difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 1 and 4 appear to be identical in scope. Independent claim 1 recites that  $R_1$  is a carbohydrate which may be one or more amino sugars, deoxy sugars, or sialic acid sugars. Dependent claim 4 recites that the amino sugars, deoxy sugars, or sialic acid sugars can be carbohydrates or saccharides, i.e. appears to recite the generic terminology present in claim 1. Accordingly, dependent appears to be identical in scope with independent claim 1.

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1-4, 20, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner et al (U.S. Patent No. 3,971,736). In Example 9, Wagner et al teach a compound present in the filtrate at column 13, line 7, which is 3,4,6-tri-O-acetyl-2-deoxy-2-acetamidoglucopyranosyl-DPhe-Pro-Phe-Phe-Val-DLeu-OEt. Treatment of the resin with methanol-triethylamine results in removal of the compound from the resin on which it has been synthesized in the form of an ethyl ester (see column 3, lines 13-22) without removal of the acetyl groups from the 2-deoxy-2-acetamidoglucopyranosyl substituent. Note that every available hydroxyl group present in the 2-deoxy-2-acetamidoglucopyranosyl substituent is modified by acetylation, which acetyl groups are not removed until the NaOH treatment at column 13, lines 8-10. The compound of Wagner et al corresponds to Applicants' Formula I in which  $m=1$ ;  $R_1$  is 3,4,6-tri-O-acetyl-2-deoxy-2-acetamidoglucopyranosyl;  $R_2$  is NH;  $R_3$  is a linker which is arylalkyl (i.e., the phenyl-CH<sub>2</sub>-CH from the DPhe residue); and NH- $R_4$ -C(=O)-NH-( $R_5$ )<sub>n</sub>-CO is Pro-Phe-Phe-Val-DLeu. In view of the similarity in structure between the

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compound of Wagner et al and Applicant's claimed compounds, inherently the compound of Wagner et al will have increased stability in the presence of peptidases and proteases, increased thermal stability, increased dimer half-life, increased bioavailability, and increased plasma half-life in comparison to a non-glycosylated analog, and inherently the 3,4,6-tri-O-acetyl-2-deoxy-2-acetamidoglucopyranosyl will serve as a stable surrogate for a specific amino acid residue to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the compound of Wagner et al and Applicants' claimed compounds to shift the burden to Applicants to provide evidence that their claimed compounds are unobviously different than the compound of Wagner et al. Note that a difference in intent or descriptive terminology does not impart novelty or nonobviousness to product claims where the claimed product is otherwise taught by the prior art.

9. Applicant's arguments filed March 17, 2010 have been fully considered but they are not persuasive.

Applicants did not respond to the rejection under 35 U.S.C. 112, second paragraph, concerning the interpretation of Formula I, and in particular of the R<sub>4</sub> and R<sub>5</sub> groups and the adjacent NH and C(=O) groups.

With the withdrawal of the rejections based upon Danishefsky et al (U.S. Patent Application Publication 2004/01026070 and Wagstaff et al (U.S. Patent No. 6,525,021) (see below), the issue of priority under 35 U.S.C. 119(e) is moot.

The anticipation rejection over the Powell et al article (Pharm. Res., Vol. 10, pages 1268-1273) is withdrawn. In view of the amendments to the claims and Applicants' arguments at page 15, fourth paragraph, lines 5-6, it is now clear that Applicants' claims require any hydroxyl,

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amino, or carboxyl functions which are present on the carbohydrate molecule to be modified.

The Powell et al article does not teach or render obvious modifying every hydroxyl function which is present in the GlcNac moiety. For analogous reasons, the anticipation rejections based upon Danishefsky et al (U.S. Patent Application Publication 2004/0102607) and Wagstaff et al (U.S. Patent No. 6,525,021) are withdrawn because the references do not teach a carbohydrate in which any hydroxyl, amino or carboxyl group is modified at the time of their attachment to a peptide.

With respect to the prior art rejections set forth in the previous Office action, Applicants contend that their claims are drawn to non-naturally occurring compounds, and that the prior art compounds comprise naturally occurring carbohydrate motifs. It should be noted that the instant claims do not require the compounds to be non-naturally occurring, and do not require R<sub>1</sub> to be something other than a naturally occurring carbohydrate motif. Patentability must be based upon claimed, not unclaimed, differences over the prior art. In any event, the 3,4,6-tri-O-acetyl-2-deoxy-2-acetamidoglucopyranosyl substituent present in Wagner et al's compound is not a naturally occurring carbohydrate.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/

Primary Examiner, Art Unit 1654

JRussel

May 25, 2010